4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 203

[Docket No. FDA-2020-N-1819]

RIN 0910-AH56

Certain Requirements Regarding Prescription Drug Marketing

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend certain prescription drug marketing regulations to reflect changes to affected provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) resulting from enactment of the Drug Supply Chain Security Act (DSCSA), Title II of the Drug Quality and Security Act (DQSA). This action, if finalized, will remove or revise outdated and conflicting regulatory requirements to align with changes to affected provisions of the FD&C Act following enactment of the DSCSA.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Electronic comments must be submitted on or before that date. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2020-N-1819 for "Certain Requirements Regarding Prescription Drug Marketing." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly available at https://www.regulations.gov, or

at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Aaron Weisbuch, Center for Drug Evaluation and Research, Office of Compliance, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-3130, WDD3PLrequirements@fda.hhs.gov.

With regard to biologics: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing to amend part 203 (21 CFR part 203) to reflect changes to affected provisions of the FD&C Act following enactment of the DSCSA, Title II of the DQSA (Pub. L. 113-54). In this proposed rulemaking, we are proposing to amend certain provisions of part 203 to avoid potential confusion with the new standards and requirements for wholesale distributors applicable under the FD&C Act (as amended by the DSCSA), and to make certain related, conforming changes.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule would: (1) modify the "scope" and "purpose" sections of the regulations in part 203 to eliminate references to wholesale distribution, (2) delete Subpart E--Wholesale Distribution in its entirety, (3) delete from § 203.3 the definitions for terms that only appeared in subpart E, and (4) modify other provisions of part 203 to eliminate references to wholesale distribution to conform to the changes described above.

C. Legal Authority

We are issuing this proposed rule under sections 503(c), 503(e), 582, 583 and 701(a) of the FD&C Act (21 U.S.C. 353(c), 353(e), 360eee-1, 360eee-2, and 371(a)).

D. Costs and Benefits

This proposed rule is a companion to the proposed rule "National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers" (licensing standards proposed rule) which implements the national licensing standards requirements of DSCSA. The licensing standards proposed rule, which would amend part 205, is published elsewhere in this issue of the *Federal Register*. We analyze the effects of the two rules together; thus, we include the benefits and costs of this proposed rule in the regulatory impact analysis of the licensing standards proposed rule.

II. Table of Abbreviations/Commonly Used Acronyms in this Document

Abbreviation/Acronym	What It Means
CFR	Code of Federal Regulations
DSCSA	Drug Supply Chain Security Act
DQSA	Drug Quality and Security Act
FDA or the Agency	U.S. Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
U.S.C.	United States Code

III. Background

A. Introduction

The DQSA was enacted on November 27, 2013. The DQSA contains two titles: Title I, the Compounding Quality Act and Title II, the DSCSA. The DSCSA amended Chapter V of the FD&C Act by adding Subchapter H (Pharmaceutical Distribution Supply Chain), which includes new sections 581 through 585 (21 U.S.C. 360eee through 360eee-4), and by amending section 503(e) of the FD&C Act. As amended, section 503(e) of the FD&C Act, together with new section 583 of the FD&C Act, require the Secretary of Health and Human Services (Secretary)[1] to establish national prescription drug wholesale distributor licensure standards. In addition, section 582 of the FD&C Act establishes prescription drug product tracing requirements for wholesale distributors and their trading partners. FDA is proposing to revise the regulations in part 203 by removing or amending those sections of the regulations that have been affected by the changes to the FD&C Act through the enactment of the DSCSA.

B. Need for the Regulation

This rulemaking, when finalized, would: (1) remove existing regulations regarding wholesale distribution of prescription drugs that conflict with or were superseded by new requirements established under the DSCSA; (2) modify other existing regulations for consistency with the regulations on standards for licensure of wholesale distributors that FDA is proposing pursuant to section 583 of the FD&C Act; and (3) make certain related, conforming changes. This rulemaking is needed to remove outdated regulations and to prevent confusion about requirements for wholesale distributors under the FD&C Act.

[1] This function has been delegated to FDA.

IV. Legal Authority

The Agency is proposing this rule under the authority to impose requirements regarding prescription drug marketing and wholesale drug distribution granted to it under various sections of the FD&C Act, including sections 503(c), 503(e), 582, 583, and 701(a). Section 503(c) describes certain restrictions on prescription drug marketing, including relating to the sale of drug samples and of drugs that have been purchased by hospitals or other healthcare entities. Section 503(e), together with section 583 of the FD&C Act, require the Secretary to establish national prescription drug wholesale distributor licensure standards, while section 582 describes requirements applicable to wholesale distributors and other entities related to product tracing. Section 701(a) provides general authority to issue regulations for the efficient enforcement of the FD&C Act. By clarifying provisions related to prescription drug marketing and by removing provisions relating to wholesale distribution, this rule, when finalized, is expected to aid in the efficient enforcement of the FD&C Act.

V. Description of the Proposed Rule

This proposed rule would make the deletions and changes to the existing regulations in part 203 discussed below as well as technical changes for clarity.

1. Scope and Purpose (§§ 203.1 and 203.2)

Existing §§ 203.1 and 203.2 describe the scope and purpose of the regulations in part 203, respectively. The proposed revisions would narrow the scope and purpose descriptions in light of the proposed elimination of requirements relating to wholesale distributors from part 203. We plan to address the standards and requirements related to wholesale distributor licensing elsewhere in our regulations, in accordance with the applicable provisions of the FD&C Act (as amended by the DSCSA).

2. Definitions (§ 203.3)

Certain definitions that currently appear in this section would be modified or eliminated.

a. Authorized distributor of record. The amendments to section 503(e) effectuated by the DSCSA eliminated the definition of "authorized distributors of record" from section 503(e) of the FD&C Act, which previously provided that the definition applied for the purposes of section 503(d) and 503(e). However, the DSCSA added a definition of the same term in section 503(d) of the FD&C Act, which relates to drug sample distribution, in section 503(d)(4). The "authorized distributor of record" definition in § 203.3 would be revised to reflect the fact that, as used in the amended part 203, the phrase would relate solely to distribution of drug samples. The revised "authorized distributor of record" definition would be found in the new § 203.3(a). In addition, as further discussed below, references to distribution of products by authorized distributors of record would be amended throughout the text of part 203, where appropriate, to clarify that these references relate only to distribution of drug samples.

b. Emergency medical reasons. The proposed rule would amend the definition of "emergency medical reasons" in the new § 203.3(l). Section 203.22, which sets forth exemptions from the sales restrictions described in § 203.20, generally provides an exemption from those restrictions for sales, purchases, or trades of a drug for emergency medical reasons (§ 203.22(d)). Section 203.3(m) currently states, in part, that "emergency medical reasons" include, but are not limited to, transfers of a prescription drug between healthcare entities or from a healthcare entity to a retail pharmacy *to alleviate a temporary shortage* of a prescription drug arising from delays in or interruption of regular distribution schedules, as well as transfers of prescription drugs by a retail pharmacy to another retail pharmacy *to alleviate a temporary shortage*. As a result, under § 203.22(d) such transfers to alleviate temporary shortages are exempt from the sales restrictions set forth in § 203.20. Certain of those transfers may, however, constitute "wholesale distribution" as defined in the DSCSA (section 503(e)(4) of the FD&C Act) because, while the "wholesale distribution" definition generally excludes distributions for "emergency medical reasons," it states that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason. With certain exceptions, a person

cannot simultaneously be a healthcare entity and a wholesale distributor (see § 203.3(p)). Because of this, FDA proposes to amend relevant language in the "emergency medical reasons" definition to clarify the relationship between it and the definition of "wholesale distribution" in section 503(e)(4) of the FD&C Act. In particular, we would add text to § 203.3(l) to make clear that a transfer made to alleviate a temporary shortage would generally be considered to be for "emergency medical reasons" for purposes of part 203 only where the transfer was either to fulfill a specific patient need or where the shortage was caused by a public health emergency (that is, where such transfers would not constitute "wholesale distribution" as defined in section 503(e)(4) of the FD&C Act). As explained in our companion proposed rulemaking for part 205 (21 CFR part 205), the Agency considers the transfer or sale of a drug from one dispenser to another dispenser made to fulfill a specific patient need to be outside the scope of the "wholesale distribution" definition in section 503(e)(4) of the FD&C Act.

c. Unauthorized distributor and wholesale distribution. The definitions of "unauthorized distributor" and "wholesale distribution," currently codified in § 203.3(bb) and (cc), respectively, would be eliminated from part 203, because these terms would no longer appear in part 203, as amended. The definition of the term "wholesale distributor" would be modified to indicate that the term would have the meaning set forth in section 581(29) of the FD&C Act.

3. Exclusions (§ 203.22(h) and (i))

Paragraphs (h) and (i) of § 203.22, which set forth exemptions from the sales restrictions in § 203.20, would be modified to eliminate the phrase indicating that the applicable requirements for a wholesale distributor or retail pharmacy are contained in part 203, because FDA is proposing to remove § 203.50, as discussed in section V.5.

4. Subpart D--Samples

FDA would replace the term "distributor" where it appears in subpart D with the phrase "authorized distributor of record" where that phrase is not already used (§§ 203.30, 203.31,

203.34, 203.36, and 203.37). As noted above, the DSCSA added a definition of "authorized distributors of record" in section 503(d) of the FD&C Act, which relates to drug sample distribution.

5. Subpart E--Wholesale Distribution

FDA proposes to remove § 203.50 (Subpart E--Wholesale Distribution) in its entirety. On July 14, 2011, FDA proposed to remove § 203.50(a) (76 FR 41434). Before that rulemaking was finalized, the DSCSA was enacted. The DSCSA replaced section 503(e)(1)-(3) of the FD&C Act and added additional and different requirements for wholesale distributors. The DSCSA also added new requirements for wholesale distributors, including phased-in prescription drug tracing requirements in section 582(c) of the FD&C Act. FDA is withdrawing the above referenced July 14, 2011, proposed rule in a document published elsewhere in this issue of the *Federal Register*. In accordance with the changes in statutory authorities, FDA proposes to remove § 203.50 in its entirety. FDA is proposing new requirements for wholesale distributors and wholesale distribution consistent with the relevant provisions of the DSCSA in a separate proposed rulemaking for part 205, also published in this issue of the *Federal Register*.

VI. Proposed Effective Date

This regulation, if finalized as proposed, will be effective 30 calendar days after the date the final rule publishes in the *Federal Register*.

VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts;

and equity). We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule imposes only minimal one-time costs of less than $100 per entity to read and understand the rule on small entities, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

We include the costs to read and understand this proposed rule in the regulatory impact analysis of the companion licensing standards proposed rule. The full preliminary analysis of economic impacts of both rules is available at https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm under "National Standards for Licensing of Prescription Drug Wholesale Distributor and Third Party Logistics Providers" (Ref. 1).

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30 that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination with Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. Reference

The following reference is on display in the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at https://www.regulations.gov. FDA has verified the website address, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for Certain Requirements Regarding Prescription Drug Marketing; Proposed Rule, available at https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

List of Subjects in 21 CFR Part 203

Labeling, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 203 be amended as follows:

PART 203--PRESCRIPTION DRUG MARKETING

1. The authority citation for part 203 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 351, 352, 353, 360, 371, 374, 381.

2. In part 203, remove the words "the act" wherever they appear and add in their place "the Federal Food, Drug, and Cosmetic Act".

3. Revise § 203.1 to read as follows:

§ 203.1 Scope.

This part sets forth procedures and requirements pertaining to the reimportation of prescription drugs, including both bulk drug substances and finished dosage forms; the sale, purchase, or trade of (or the offer to sell, purchase, or trade) prescription drugs, including bulk drug substances, that were purchased by hospitals or healthcare entities, or donated to charitable organizations; and the distribution of prescription drug samples. For purposes of this part, the term "prescription drug" has the meaning set forth in § 203.3(x).

4. Revise § 203.2 to read as follows:

§ 203.2 Purpose.

The purpose of this part is to protect the public against drug diversion and enhance the security of the drug supply chain by establishing procedures and requirements relating to the

reimportation of prescription drugs, the distribution of prescription drug samples, and the sale, purchase, or trade of prescription drugs purchased by hospitals or healthcare entities or donated to charitable organizations.

5. Revise § 203.3 to read as follows:

§ 203.3 Definitions.

(a) *Authorized distributor of record* means a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's drug samples.

(b) *Blood* means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(c) *Blood component* means that part of a single-donor unit of blood separated by physical or mechanical means.

(d) *Bulk drug substance* means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

(e) *Charitable institution* or *charitable organization* means a nonprofit hospital, healthcare entity, organization, institution, foundation, association, or corporation that has been granted an exemption under section 501(c)(3) of the Internal Revenue Code of 1954, as amended.

(f) *Common control* means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise.

(g) *Distribute* means to sell, offer to sell, deliver, or offer to deliver a drug to a recipient, except that the term "distribute" does not include:

(1) Delivering or offering to deliver a drug by a common carrier in the usual course of business as a common carrier; or

(2) Providing of a drug sample to a patient by:

(i) A practitioner licensed to prescribe such drug;

(ii) A healthcare professional acting at the direction and under the supervision of such a practitioner; or

(iii) The pharmacy of a hospital or of another healthcare entity that is acting at the direction of such a practitioner and that received such sample in accordance with the Federal Food, Drug, and Cosmetic Act and the regulations in this part.

(h) *Drug sample* means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(i) *Drug coupon* means a form that may be redeemed, at no cost or at reduced cost, for a drug that is prescribed in accordance with section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(j) *Electronic record* means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

(k) *Electronic signature* means any computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

(l) *Emergency medical reasons* include, but are not limited to:

(1) Transfers of a prescription drug between healthcare entities or from a healthcare entity to a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules, provided that such transfers are made in order to fulfill a specific patient need or respond to a public health emergency;

(2) Sales to nearby emergency medical services, i.e., ambulance companies, police, and fire-fighting organizations in the same State or same marketing or service area, or nearby licensed practitioners, of drugs for use in the treatment of acutely ill or injured persons;

(3) Provision of minimal emergency supplies of drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary drugs cannot be obtained; and

(4) Transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, provided that such transfers are made in order to fulfill a specific patient need or respond to a public health emergency but do not include regular and systematic sales to licensed practitioners of prescription drugs that will be used for routine office procedures.

(m) *FDA* means the U.S. Food and Drug Administration.

(n) *Group purchasing organization* means any entity established, maintained, and operated for the purchase of prescription drugs for distribution exclusively to its members with such membership consisting solely of hospitals and healthcare entities bound by written contract with the entity.

(o) *Handwritten signature* means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark.

(p) *Healthcare entity* means any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor. Except as provided in §203.22(h) and (i), a person cannot simultaneously be a “healthcare entity” and a retail pharmacy or wholesale distributor.

(q) *Licensed practitioner* means any person licensed or authorized by State law to prescribe drugs.

(r) *Manufacturer* means any person who is a manufacturer as defined by §201.1 of this chapter.

(s) *Nonprofit affiliate* means any not-for-profit organization that is either associated with or a subsidiary of a charitable organization as defined in section 501(c)(3) of the Internal Revenue Code of 1954.

(t) *Ongoing relationship* means an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's drug samples for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer's entire drug sample line, the agreement must identify the specific drug samples that the distributor is authorized to distribute.

(u) *PDA* means the Prescription Drug Amendments of 1992.

(v) *PDMA* means the Prescription Drug Marketing Act of 1987.

(w) *Person* includes any individual, partnership, corporation, or association.

(x) *Prescription drug* means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by Federal law (including Federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(y) *Representative* means an employee or agent of a drug manufacturer or authorized distributor of record who promotes the sale of prescription drugs to licensed practitioners and who may solicit or receive written requests for the delivery of drug samples. A detailer is a representative.

(z) *Sample unit* means a packet, card, blister pack, bottle, container, or other single package comprised of one or more dosage units of a prescription drug sample, intended by the manufacturer or authorized distributor of record to be provided by a licensed practitioner to a patient in an unbroken or unopened condition.

(aa) *Wholesale distributor* has the meaning set forth in section 581(29) of the Federal Food, Drug, and Cosmetic Act.

6. In § 203.22, revise paragraphs (h) and (i) to read as follows:

§ 203.22 Exclusions.

* * * * *

(h) The sale, purchase, or trade of, or the offer to sell, purchase, or trade, by a registered blood establishment that qualifies as a healthcare entity, any:

(1) Drug indicated for a bleeding or clotting disorder, or anemia;

(2) Blood collection container approved under section 505 of the Federal Food, Drug, and Cosmetic Act; or

(3) Drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative); as long as all of the healthcare services that the establishment provides are related to its activities as a registered blood establishment or the healthcare services consist of collecting, processing, storing, or administering human hematopoietic stem/progenitor cells or performing diagnostic testing of specimens provided that these specimens are tested together with specimens undergoing routine donor testing. Blood establishments relying on the exclusion in this paragraph (h)(3) must satisfy all other applicable requirements of the Federal Food, Drug, and Cosmetic Act and the regulations in this part promulgated thereunder.

(i) The sale, purchase, or trade of, or the offer to sell, purchase, or trade, by a comprehensive hemophilia diagnostic treatment center that is receiving a grant under section 501(a)(2) of the Social Security Act and that qualifies as a healthcare entity, any drug indicated for a bleeding or clotting disorder, or anemia, or any drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative). Comprehensive hemophilia diagnostic treatment centers relying on the exclusion in this paragraph (i) must satisfy all other applicable requirements of the Social Security Act and the regulations in this part promulgated thereunder.

7. In § 203.30, revise paragraphs (a)(4) and (c) to read as follows:

§ 203.30 Sample distribution by mail or common carrier.

(a) * * *

(4) The receipt is returned to the manufacturer or authorized distributor of record from which the drug sample was received.

* * * * *

(c) *Contents of the receipt to be completed upon delivery of a drug sample*. The receipt is to be on a form designated by the manufacturer or authorized distributor of record, and is required to contain the following:

(1) If the drug sample is delivered to the licensed practitioner who requested it, the receipt is required to contain the name, address, professional title, and signature of the practitioner or the practitioner's designee who acknowledges delivery of the drug sample; the proprietary or established name and strength of the drug sample; the quantity of the drug sample delivered; and the date of the delivery.

(2) If the drug sample is delivered to the pharmacy of a hospital or other healthcare entity at the request of a licensed practitioner, the receipt is required to contain the name and address of the requesting licensed practitioner; the name and address of the hospital or healthcare entity pharmacy designated to receive the drug sample; the name, address, professional title, and signature of the person acknowledging delivery of the drug sample; the proprietary or established name and strength of the drug sample; the quantity of the drug sample delivered; and the date of the delivery.

8. In § 203.31, revise paragraphs (a)(4), (c), (d) introductory text, (d)(2)(iii), and (e) to read as follows:

§ 203.31 Sample distribution by means other than mail or common carrier (direct delivery by a representative or detailer).

(a) * * *

(4) The receipt is returned to the manufacturer or authorized distributor of record; and

* * * * *

(c) *Contents of the receipt to be completed upon delivery of a drug sample*. The receipt is to be on a form designated by the manufacturer or authorized distributor of record, and is required to contain the following:

(1) If the drug sample is received at the address of the licensed practitioner who requested it, the receipt is required to contain the name, address, professional title, and signature of the practitioner or the practitioner's designee who acknowledges delivery of the drug sample; the proprietary or established name and strength of the drug sample; the quantity of the drug sample delivered; and the date of the delivery.

(2) If the drug sample is received by the pharmacy of a hospital or other healthcare entity at the request of a licensed practitioner, the receipt is required to contain the name and address of the requesting licensed practitioner; the name and address of the hospital or healthcare entity pharmacy designated to receive the drug sample; the name, address, professional title, and signature of the person acknowledging delivery of the drug sample; the proprietary or established name and strength of the drug sample; the quantity of the drug sample delivered; and the date of the delivery.

(d) *Inventory and reconciliation of drug samples of manufacturers' and authorized distributors' representatives*. Each drug manufacturer or authorized distributor of record that distributes drug samples by means of representatives shall conduct, at least annually, a complete and accurate physical inventory of all drug samples. All drug samples in the possession or control of each manufacturer's and authorized distributor's representatives are required to be inventoried and the results of the inventory are required to be recorded in an inventory record, as specified in paragraph (d)(1) of this section. In addition, manufacturers and authorized distributors of record shall reconcile the results of the physical inventory with the most recently completed prior physical inventory and create a report documenting the reconciliation process, as specified in paragraph (d)(2) of this section.

* * * * *

(2) * * *

(iii) A record of drug sample distributions since the most recently completed inventory showing the name and address of each recipient of each sample unit shipped, the date of the shipment, and the proprietary or established name, dosage strength, and number of sample units shipped. For the purposes of this paragraph (d)(2)(iii) and paragraph (d)(2)(v) of this section, "distributions" includes distributions to healthcare practitioners or designated hospital or healthcare entity pharmacies, transfers or exchanges with other firm representatives, returns to the manufacturer or authorized distributor of record, destruction of drug samples by a sales representative, and other types of drug sample dispositions. The specific type of distribution must be specified in the record;

* * * * *

(e) *Lists of manufacturers' and authorized distributors' representatives.* Each drug manufacturer or authorized distributor of record who distributes drug samples by means of representatives shall maintain a list of the names and addresses of its representatives who distribute drug samples and of the sites where drug samples are stored.

9. In § 203.34, revise paragraph (b)(1) to read as follows:

§ 203.34 Policies and procedures; administrative systems.

* * * * *

(b) * * *

(1) Reconciling requests and receipts, identifying patterns of nonresponse, and the manufacturer's or authorized distributor of record's response when such patterns are found;

* * * * *

10. In § 203.36, revise paragraph (a) to read as follows:

§ 203.36 Fulfillment houses, shipping and mailing services, comarketing agreements, and third-party recordkeeping.

(a) *Responsibility for creating and maintaining forms, reports, and records*. Any manufacturer or authorized distributor of record that uses a fulfillment house, shipping or mailing service, or other third party, or engages in a comarketing agreement with another manufacturer or authorized distributor of record to distribute drug samples or to meet any of the requirements of PDMA, PDA, or this part, remains responsible for creating and maintaining all requests, receipts, forms, reports, and records required under PDMA, PDA, and this part.

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11. In §203.37, revise paragraph (e) to read as follows:

§ 203.37 Investigation and notification requirements.

* * * * *

(e) *Whom to notify at FDA*. Notifications and reports concerning samples of human prescription drugs or biological products that are regulated by the Center for Drug Evaluation and Research shall be made via email to PDMAREPORTS@fda.hhs.gov. Alternatively, reports and correspondence concerning such samples may be made via regular mail to the Office of Drug Security, Integrity, and Response, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993-0002, ATTN: PDMA Reports. Notifications and reports concerning samples of human prescription biological products regulated by the Center for Biologics Evaluation and Research shall be made to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002.

Subpart E [Removed and Reserved]

12. Remove and reserve subpart E, consisting of § 203.50.

Dated: January 24, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

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